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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,544	04/01/2004	Kevin D. Kreutter	3DP-0548	1002
23377 7590 08/09/2007 WOODCOCK WASHBURN LLP CIRA CENTRE, 12TH FLOOR 2929 ARCH STREET PHILADELPHIA, PA 19104-2891			EXAMINER OH, TAYLOR V	
			ART UNIT 1625	PAPER NUMBER
			MAIL DATE 08/09/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/816,544

Applicant(s)

KREUTTER ET AL.

Examiner

Taylor Victor Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) 36-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-35, 64-71 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The previous Office Action has been withdrawn ; the examiner has decided to apply the restriction again based on the previously elected group (II) (claims 1-35 and 64-71) in view of the amendment.

The Status of Claims :

Claims 1-71 are pending.

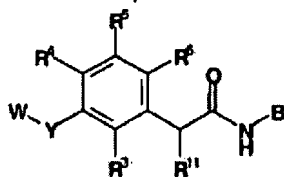
Claims 36-63 are withdrawn.

Claims 1-35 and 64-71 have been subject to the restriction requirement.

Election/Restriction

A. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-35 and 64-71, drawn to compounds of formula (1) of heterocyclic substituents having a cyclic carbonate, and their pharmaceutical composition:



wherein

W is R^1 or $R^1S(O_2)$;

R^1 is

R^2 , $(R^2)_2CH(CH_2)_r$, $(R^2)_2$ can also form a ring with

a 5- to 7-membered mono- or bicyclic heterocyclic ring ; $(R^2)_2CF(CH_2)_r$,

$(R^2)_2$ can also form a ring with

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a 5- to 7-membered mono- or bicyclic heterocyclic ring

Y is -NH- or O;

R³ is hydrogen, halogen or OH;

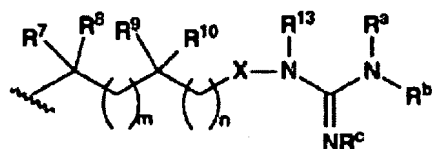
R⁴ and R⁵ are independently hydrogen, halogen, alkyl, alkenyl, alkynyl, hydroxy, alkoxy, haloalkyl, haloalkoxy, hydroxyalkyl, cyano, nitro, -CO₂R^x, -CH₂OR^x or -OR^x, where

R^x, in each instance, is independently one of hydrogen or C₁₋₆ alkyl;

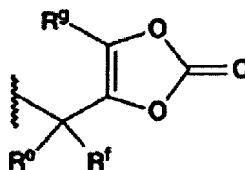
R⁶ is cyano or acetylenyl;

R¹¹ is hydrogen, halogen or alkyl;

B is selected from the group consisting of



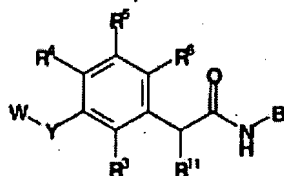
, wherein



R^a, R^b and R^c are -CO₂R^w, R^w is

classified in class 549, subclass 229;

II. Claims 1-35 and 64-71, drawn to compounds of formula (1) of heterocyclic substituents having a pyridine group, and their pharmaceutical composition:

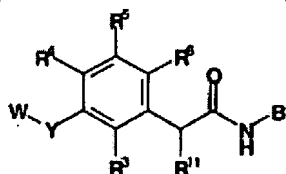


classified in class 546, subclass 93;

III. Claims 1-35 and 64-71, drawn to compounds of formula (1) of heterocyclic substituents having a pyridyl-n-oxy group

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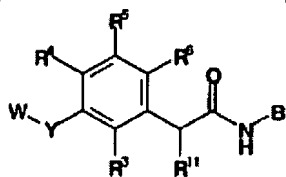
, and their pharmaceutical composition:



classified in class 546, subclass 152;

IV. Claims 1-35 and 64-71, drawn to compounds of formula (1) of heterocyclic substituents having 1,3-oxazole group

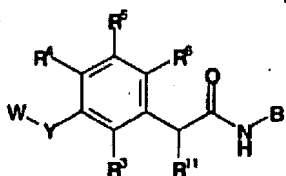
, and their pharmaceutical composition:



classified in class 548, subclasses 240;

V. Claims 1-35 and 64-71, drawn to compounds of formula (1) of heterocyclic substituents having tetrazoly group.

, and their pharmaceutical composition:



classified in class 549, subclass 229.

1. The inventions are distinct, each from the other because of the following reasons: Inventions I - II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case there are two different inventions I and II. The invention I is related to compounds of formula (1) of heterocyclic substituents with the side chain groups of the heterocyclic compound having a cyclic carbonate, **whereas the invention II is related to** compounds of formula (1) of heterocyclic substituents with the side chain groups of the heterocyclic compounds contain different kinds of heterocycles, such as pyridy group.

They have different structures and different functional groups in the ring, thereby exhibiting a chemically different activity respectively. Furthermore, they are classified in different classes and subclasses; therefore, it is a burden for the examiner to search those broad classes and subclasses. In addition, each invention has a different use and effect due to unrelated substituents attached to the core of the compounds.

2. The inventions are distinct, each from the other because of the following reasons: Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case there are two different inventions I and III. The invention I is related to compounds of formula (1) of heterocyclic substituents with the side chain groups of the heterocyclic compound having a cyclic carbonate, **whereas the invention III is related to** compounds of formula (1) of heterocyclic substituents with

the side chain groups of the heterocyclic compounds contain different kinds of heterocycles, such as pyridyl-n-oxy group.

They have different structures and different functional groups in the ring, thereby exhibiting a chemically different activity respectively. Furthermore, they are classified in different classes and subclasses; therefore, it is a burden for the examiner to search those broad classes and subclasses. In addition, each invention has a different use and effect due to unrelated substituents attached to the core of the compounds.

3. The inventions are distinct, each from the other because of the following reasons: Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case there are two different inventions I and IV. The invention I is related to compounds of formula (1) of heterocyclic substituents with the side chain groups of the heterocyclic compound having a cyclic carbonate, whereas the invention IV is related to compounds of formula (1) of heterocyclic substituents with the side chain groups of the heterocyclic compounds contain different kinds of heterocycles, such as 1,3-oxazole group

They have different structures and different functional groups in the ring, thereby exhibiting a chemically different activity respectively. Furthermore, they are classified in different classes and subclasses; therefore, it is a burden for the examiner to search those broad classes and subclasses. In addition, each invention has a different use and effect due to unrelated substituents attached to the core of the compounds.

4. The inventions are distinct, each from the other because of the following reasons: Inventions I and V are unrelated. Inventions are unrelated if it can be shown that

they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case there are two different inventions I and V. The invention I is related to compounds of formula (1) of heterocyclic substituents with the side chain groups of the heterocyclic compound having a cyclic carbonate, **whereas the invention V is related to** compounds of formula (1) of heterocyclic substituents with the side chain groups of the heterocyclic compounds contain different kinds of heterocycles, such as tetrazoly group.

They have different structures and different functional groups in the ring, thereby exhibiting a chemically different activity respectively. Furthermore, they are classified in different classes and subclasses; therefore, it is a burden for the examiner to search those broad classes and subclasses. In addition, each invention has a different use and effect due to unrelated substituents attached to the core of the compounds.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

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the prior art, the evidence or admission may be used in a rejection under 35

U.S.C. 103(a) of the other invention.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II-V, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Taylor Victor Oh, MSD.LAC
Primary Examiner
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